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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,499	12/19/2005	Toshihiro Shirouzu	KUZ00027US.NP	9337

7590
Licata & Tyrrell
66 East Main Street
Marlton, NJ 08053

EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1612

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09/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,499	Applicant(s) SHIROUZU ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-19 is/are pending in the application.
- 4a) Of the above claim(s) 3,6,8 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 7, 9-12 and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20 March 2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed March 20, 2008. All previous rejections have been withdrawn unless stated below.

Election by Original Presentation

Amended claim 6 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 23, 2007.

Claims

Claim Rejections - 35 USC § 102 – Anticipation (New Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1, 2, 7 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sun et al. (US 6,231,875).

Sun et al. disclose topical compositions for treating human nail and skin diseases, including fungal infections, bacterial infections and psoriatic infections. These

infections include plantar tinea pedis and athlete's foot. Active agents include miconazole, ketoconazole, butenafine, tolnaftate and terbinafine. The preferred compounds are terbinafine and naftifine (col. 4, lines 58-66). These agents comprise about 0.05% to 10% w/w (col. 6, lines 3-7). The compositions may also comprise menthol which comprises 1% w/w (Table 10).

2) Claims 1, 2, 4, 7, 9-12 and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoki et al. (JP 2002-284702, Publication date October 3, 2002).

Aoki et al. disclose topical compositions for treating conditions such as athlete's foot comprising an antifungal, antihistamine, terpenes and urea. Antifungals include miconazole, ketoconazole, neticonazole, butenafine and terbinafine, encompassing the instant claims. They comprise 0.1 to 30% by mass. Terpenes include menthol, encompassing the instant claims. Terpenes comprise 0.1 to 10% by mass. One composition includes a cream prepared by mixing (in g) thioconazole (1.0), diphenhydramine (1.0) encompassing claims 11 and 19; urea (5.0); 1-menthol (3.0); isopropyl methyl phenol (0.3 g) encompassing claims 4 and 14-19; lidocaine (2.5) encompassing claims 9, 10 and 19; glycyrrhetic acid (0.5) encompassing claims 12, 15 and 19, propylene glycol (5.0), monostearic acid glycerin (3.0), polyoxyethyl cetyl alcohol (3.0), stearyl alcohol (4.0), cetanol (4.0), triglycerine (capryl and capric acid) (4.0) and purified water (See Derwent Abstract 2003-203940).

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 4, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (US 6,231,875) as applied to claims 1, 2, 7 and 16 above in further view of Kuhner et al. (US 2003/0194445).

Sun et al. is discussed above. The reference differs from the instant claims insofar as it does not disclose the compositions comprise isopropylmethylphenol.

Kuhner et al. disclose an isopropylmethylphenol composition, to be administered topically, for the treatment of athlete's foot (paragraphs 0056, 0066 and 0083). Isopropylmethylphenol is used as a germicide or preservative (paragraph 0056). The reference differs from the instant claims insofar as it does not disclose the compositions comprise an antifungal agent of the instant claims.

It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". See MPEP 2144.06. It would have been obvious to one of ordinary skill in the art to have combined the compositions of the references into one composition motivated by the desire to treat different symptoms associated with athlete's foot, as supported by cited precedent.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art at to have incorporated isopropylmethylphenol into the compositions of Sun et al.

motivated by the desire to treat athlete's foot with an ingredient disclosed by the art as effective in treating the condition and for its known function as a germicide, as supported by MPEP 2144.07 and Kuhner et al.

2) Claims 9, 10, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (US 6,231,875) as applied to claims 1, 2, 7 and 16 above in further view of Packman (US 4,945,084).

Sun et al. is discussed above. The reference differs from the instant claims insofar as it does not disclose the compositions comprise dibucaine hydrochloride.

Packman discloses a topical treatment for athlete's foot comprising dibucaine hydrochloride. Dibucaine relieves pain, burning, itching, and discomfort (abstract; column 5, lines 19-25; and column 6, lines 12-14). The reference differs from the instant claims insofar as it does not disclose the compositions comprise an antifungal agent of the instant claims and menthol.

It would have been obvious to one of ordinary skill in the art to have combined the compositions of the references into one composition motivated by the desire to treat different symptoms associated with athlete's foot, as supported by cited precedent. See MPEP 2144.06 as cited in subsection 1.

It would have been obvious to one of ordinary skill in the art to have incorporated dibucaine hydrochloride into the compositions of Sun et al. motivated by the desire to treat athlete's foot with an ingredient disclosed by the art as effective in

treating the condition and for its known function of relieving pain, burning, itching and discomfort, as supported by MPEP 2144.07 and Packman. See MPEP 2144.07 as cited in subsection 1.

3) Claims 9, 11, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (US 6,231,875) as applied to claims 1, 2, 7 and 16 above in further view Blackman (US 4,873,265).

Sun et al. is discussed above. The reference differs from the instant claims insofar as it does not disclose the compositions comprise chlorpheniramine maleate.

Blackman discloses a topical antihistamine-containing composition for the treatment of athlete's foot (column 3, lines 55-65). The antihistamine may be chlorpheniramine maleate, which acts as an antibacterial agent (column 7, line 4). The reference differs from the instant claims insofar as it does not disclose the compositions comprise an antifungal agent of the instant claims and menthol.

It would have been obvious to one of ordinary skill in the art to have combined the compositions of the references into one composition motivated by the desire to treat different symptoms associated with athlete's foot, as supported by cited precedent. See MPEP 2144.06 as cited in subsection 1.

It would have been obvious to one of ordinary skill in the art to have incorporated chlorpheniramine maleate into the compositions of Sun et al. motivated by the desire to treat athlete's foot with an ingredient disclosed by the art as effective in treating the condition and for its known function as an antihistamine and antibacterial

agent, as supported by MPEP 2144.07 and Blackman. See MPEP 2144.07 as cited in subsection 1.

4) Claims 9, 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (US 6,231,875) as applied to claims 1, 2, 7 and 16 above in further view of Mekata (US 6,581,807).

Sun et al. is discussed above. The reference differs from the instant claims insofar as it does not disclose the compositions comprise glycyrrhetic acid or allantoin.

Mekata discloses an aerosol product for the treatment of athlete's foot comprising a composition of glycyrrhetic acid and allantoin as inflammation inhibitors (column 5, line 36; and column 7, lines 28-33). It would be obvious that the aerosol composition may be administered topically. For example the aerosol composition for athlete's foot may be a spray to be applied to the affected foot. The reference differs from the instant claims insofar as it does not disclose the compositions comprise an antifungal agent of the instant claims and menthol.

It would have been obvious to one of ordinary skill in the art to have combined the compositions of the references into one composition motivated by the desire to treat different symptoms associated with athlete's foot, as supported by cited precedent. See MPEP 2144.06 as cited in subsection 1.

It would have been obvious to one of ordinary skill in the art to have incorporated glycyrrhetic acid or allantoin into the compositions of Sun et al. motivated

by the desire to treat athlete's foot with an ingredient disclosed by the art as effective in treating the condition and for its known function as an inflammation inhibitor, as supported by MPEP 2144.07 and Mekata. See MPEP 2144.07 as cited in subsection 1.

5) Claims 14, 15, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (US 6,231,875) as applied to claims 1, 2, 7 and 16 above in further view of Kuhner et al. (US 2003/0194445), Packman (US 4,945,084), Blackman (US 4,873,265), and Mekata (US 6,581,807).

Sun et al. is discussed above. The reference differs from the instant claims insofar as it does not disclose the compositions comprise isopropylmethylphenol, dibucaine hydrochloride, chlorpheniramine maleate, and glycyrrhetic acid.

Kuhner et al. is discussed above and differs from the instant claims insofar as it does not disclose the compositions comprise an antifungal agent of the instant claims, menthol, dibucaine hydrochloride, chlorpheniramine maleate, and glycyrrhetic acid.

Packman is discussed above in subsection 2 and differs from the instant claims insofar as it does not disclose the compositions comprise an antifungal agent of the instant claims, menthol, isopropylmethylphenol, chlorpheniramine maleate, and glycyrrhetic acid.

Blackman is discussed above in subsection 3 and differs from the instant claims insofar as it does not disclose the compositions comprise an antifungal agent of the

instant claims, menthol, isopropylmethylphenol, dibucaine hydrochloride, and glycyrrhetic acid.

Mekata is discussed above in subsection 4 and differs from the instant claims insofar as it does not disclose the compositions comprise an antifungal agent of the instant claims, menthol, isopropylmethylphenol, dibucaine hydrochloride, and chlorpheniramine maleate.

It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose” and “It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose”. See MPEP 2144.06. It would have been obvious to one of ordinary skill in the art to have combined the compositions of the references into one composition motivated by the desire to treat different symptoms associated with athlete’s foot, as supported by cited precedent.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art at to have incorporated isopropylmethylphenol, dibucaine hydrochloride, chlorpheniramine maleate, and glycyrrhetic acid into the compositions of Sun et al. motivated by the desire to treat athlete’s foot with ingredients disclosed by the art effective in treating the condition and for their known functions, as supported by MPEP 2144.07 and the cited references Kuhner et al., Packman, Blackman, and Mekata.

Claims 1, 2, 4, 7, 9-12 and 14-19 are rejected.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612